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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,905	02/23/2004	Charles Ebert	2003-001	6139

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/784,905	**Applicant(s)** EBERT, CHARLES	
	Examiner Renee Claytor	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 July 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-10, 25-36*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Applicants argue that the 35 USC 112 rejection is improper because the polyethylene glycol ranges are taught in the specification and point out paragraphs 0010, 0042-0043 and 0056-0064. However, it is noted that there is nothing in the specification that allows one to know that the specific ranges of 100-1600, 1600-5000 or 5000 to 20000 are envisioned. The specific amounts that Applicants teach in the specification are 200, 300, 400, 540 blend, 900, 1000, 1450, 3350, 4000, 4600 and 8000. But there is no teaching of 1600 or 5000 that would lead one to envision those particular amounts. Accordingly, the rejection is maintained.

Applicants arguments over the 35 103 rejection is that there is no disclosure in Riegelman et al. of a dosage form containing between 30% w/w and 80% w/w polyethylene glycol that exhibits a release that would provide a therapeutically effective testosterone serum level to a patient as recited in the present claims. Applicants also argue that Van der Vies does not disclose any dosage forms containing between 30% w/w and 80% w/w polyethylene glycol and does not provide guidance towards using specific weight ranges of specific molecular weight polyethylene glycols as recited in the present claims.

In response to the above arguments, it is noted that Riegelman et al. teaches various compounds that benefit from the invention of increasing the absorbability of drugs. Further, Riegelman et al. teaches that polyethylene glycol is a useful carrier in the invention, and teaches molecular weight ranges that overlap with that of the claimed invention. The examples are drawn to making compositions of the invention but is not limiting in what compound can be used because the reference has a whole envisions various different compounds useful in the composition. Riegelman et al. teaches compositions that include weight percentages of the polyethylene glycol that overlap with that of the claimed invention. Because Riegelman et al. did not exemplify a composition with testosterone and amounts of polyethylene glycol in amounts of 30%-80% w/w, the reference was used in an obviousness rejection because Riegelman et al. does exemplify compositions with varying ranges. Regarding the argument over the Van der Vies reference, it is noted that Van der Vies was not used to meeting the limitation of the molecular weight range of polyethylene glycol, Van der Vies was used to teach that testosterone is orally effective at concentrations that overlap with those of the present invention. Further, and as explained previously, because the same doses are taught, it is obvious that the serum levels of testosterone would fall within the 15 ng/dl to about 1200 ng/dl because this is a property of the drug. Accordingly, the rejections are maintained.